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Alexandria, VA 22313-1450

On August 15, 2005

TOWNSEND and TOWNSEND and CREW LLP

By: Sylvia Eldredge

PATENT
Attorney Docket No.: 021706-002200US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 1448
Fuchshuber et al.	Examiner: Jyothsna A. Venkat
Application No.: 10/069,448	Technology Center/Art Unit: 1615
Filed: August 7, 2002	DECLARATION
For: NON-AQUEOUS LIQUID SHAMPOO COMPOSITION	
Customer No.: 20350	

I, Albert Zorko Abram, state and declare as follows:

1. All statements herein made of my own knowledge are true, and statements made on information and belief are believed to be true and correct.

2. I am currently employed by Connetics Australia Pty Ltd, the assignee of the subject application.

3. I am employed as Senior Chemistry Supervisor & IP Support and have been in pharmaceutical research since 1987. I have been employed doing dermatological research and product development for the last 18 years. My curriculum vitae is attached as Exhibit A.

4. I have read and I am familiar with the contents of the above-referenced patent application. In addition, I have read the Office Action dated December 10, 2004 and the Advisory Action dated April 29, 2005. It is my understanding that the Examiner alleges that the claimed invention is obvious over the combination of U.S. Patent No. 5,866,152 ("the '152

patent"), PCT Publication WO 87/04617 ("the '617 publication") and U.S. Patent No. 6,207,694 ("the '694 patent"). For the reasons set forth herein, the Examiner's concerns are overcome.

5. The inventive compositions of the present application show unexpected advantageous properties when compared to the closest cited art.

6. A side-by-side comparative experiment was conducted in my laboratory. The formulation of Example 1 of the present application (inventive, Sample A) was compared to Example 3 from U.S. Patent No. 5,866,152 ("comparative," Sample B). A final sample (Sample C) was prepared based upon U.S. Patent No. 5,866,152 wherein the order of addition of the various components match more closely with the inventive sample. The foregoing formulations are set forth as Table 1 (attached).

7. Table 2 shows the results from three different formulations of the comparative experiment. Sample A is Example 1 of the present application (inventive). Sample A shows no signs of particulates or crystals present over the period of 7 days. Figures 1-3, and 10 show the formulation, stored at temperatures of 5°C, RT and 25°C, respectively.

8. Table 2 shows the results of Sample B (comparative), which is Example 3 of U.S. Patent No. 5,866,152. In contrast to paragraph 7 above, this example shows a crystalline material has settled to the bottom of the glass jar. Figures 4-6, and 11 show the results of Sample B at temperatures of 5°C, Room Temperature and 25°C.

9. Table 2 also shows the results of Sample C (comparative), which is comparative Example 3 from U.S. Patent No. 5,866,152, wherein the order of addition of the various components is more closely in accordance to the inventive formulation of the present invention. Again, at 7 days of storage, all of the samples have a 1 to 2 mm layer of crystalline material that had settled to the bottom of the glass jar. Figures 7-9, and 12 show the results of Sample C at temperatures of 5°C, Room Temperature and 25°C.

10. The results of this 7 day study show that clotrimazole remains in solution with Example 1 from the present invention (Sample A), but not with Example 3 from U.S. Patent No. 5,866,152 regardless of how it was prepared (Samples B & C).

11. It was observed that the clotrimazole did not dissolve in Example 3 from U.S. Patent No. 5,866,152 when prepared as disclosed in the patent specification. When Example 3 was prepared for a second time, following a similar manufacturing method to that outlined in the present application, the clotrimazole did dissolve initially. However, during storage, crystalline material was precipitated from the liquid and it settled to the bottom of the glass jar in which it was stored.

12. Example 3 from the U.S. Patent No. 5,866,152 was not able to produce a single-phase liquid shampoo. Clotrimazole did not dissolve in one version of Example 3 (Sample B)

which was prepared according to the method disclosed in U.S. Patent No. 5,866,152. In another version of Example 3 (Sample C), prepared according to the method disclosed in the present application, the clotrimazole did dissolve initially, but within 24 hours some crystalline material had accumulated.

13. This study demonstrates that the inventive formulation remains as a single-phase shampoo following the initial preparation. The comparative formulation, regardless of the manufacturing technique, was not able to produce a stable single-phase, crystal free liquid which remains in this state.

14. Thus, the inventive formulation remains homogeneous during dispersing whereas the comparative examples will not provide a consistent homogeneous dose of the formulation.

15. For the foregoing reasons, it is my scientific opinion that the present invention possesses unexpected advantageous properties not present in the cited art.

16. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made may jeopardize the validity of the application or any patent issuing hereon.

Albert Zorko Abram

15 August, 2005
Date

60557737 v1

Curriculum Vitae

Personal Details

Name Albert Zorko Abram

Address 3 Abbey Court
Wantirna
Victoria
Australia, 3152

Education

Post Secondary Bachelor of Science
Monash University
Completed in 1997
Master of Intellectual Property Law
Monash University
Completed in 2004

Secondary 1984
High School Certificate
Haileybury College

Work History

Job Details January 2005 – Present
Senior Chemistry Supervisor & IP Support
Connetics Australia Pty Ltd
(Change of title)
January 2003 – January 2005
Senior Chemist Technical IP Associate
Connetics Australia Pty Ltd

Responsibilities Oversee and provide technical leadership for company R&D programs in line with agreed corporate objectives
Liase with intellectual property professionals to facilitate the drafting of patent specifications
Coordinate technical activities in line with agreed intellectual property areas
Provide technical advice for intellectual property matters
Provide technical reviews of intellectual property pertinent to key in-house technologies
Keep abreast of new technologies and technical developments
Draft and issue company procedure forms to facilitate the running of the laboratory
Ensure that the company's quality systems are fully operational at all times
Interview prospective employees and train the Formulation Chemists in core scientific activities
Review of monthly technical progress reports
Provide technical service, advice and assistance to company divisions and clients
Provide technical leadership to ensure smooth and effective running of the laboratory
Provide technical advice to company staff and clients as required
To ensure all work in the laboratory is conducted in a safe manner in line with the company's safety policies

Job Details July 2001 – December 2002
Senior Chemistry Supervisor
Soltec Research Pty Ltd/Connetics Australia Pty Ltd
(Company name change to Connetics Australia Pty Ltd in October 2002)

Responsibilities
Manage formulation team projects
Prepare formulation development proposals
Prepare project plans in consultation with formulation development teams
Propose new research proposals and conduct research activities to evaluate project feasibility
Keep abreast of new technologies and technical developments
Draft and issue company procedure forms to facilitate the running of the laboratory
Ensure company's quality systems are fully operational at all times
Interview prospective employees and train the Formulation Team's personnel
To approve, allocate and coordinate projects to completion
Submission of monthly technical progress reports
Provide technical service, advice and assistance to company divisions and clients
Ensure smooth and effective running of the Dermatology/Formulation Team
Ensure an orderly and prioritised progression of all development work and provide technical advice to company staff and clients as required
To ensure all work in the laboratory is conducted in a safe manner in line with the company's safety policy
Provide technical advice for intellectual property matters

Key Achievements
Contributing author for "Barel/Maibach/Paye :Handbook of Cosmetic Science and Technology"
Primary project liaison for key product development programs

Job Details July 1999 – July 2001
Team Leader, Dermatology
Soltec Research

Responsibilities
Manage and coordinate the drafting and issue of MSDS, product specifications, manufacturing methods, product development proposals, reports and procedures.
Maintain the computer database relating to research, development and product evaluation work
Keep abreast of new technologies and technical developments
Draft and issue company procedure forms to facilitate the running of the laboratory
Ensure Soltec's quality systems are fully operational at all times
Interview prospective employees and train the Dermatology Team's personnel
To approve, allocate and coordinate projects to completion
Submission of monthly technical progress reports
Provide technical service, advice and assistance to company divisions and clients
Ensure smooth and effective running of the Dermatology Team
Ensure an orderly and prioritised progression of all development work and provide technical advice to company staff and clients as required
To ensure all work in the laboratory is conducted in a safe manner in line with the company's safety policy
Provide technical advice for intellectual property matters

Key Achievements
Primary project liaison for key product development programs

Reason for Leaving Position
Promotion

Job Details July 1988 - June 1999
R & D Scientist
Soltec Research

Responsibilities
Maintenance and purchase of laboratory equipment
Prepare and coordinate project plans
Process development
Training staff in the art of formulation chemistry
Report on research and development activities to management and clients
Research and development of pharmaceutical, cosmetic, food, household, veterinary, automotive, industrial, aerosol and agricultural products
Develop manufacturing methods and oversee pilot scale and commercial scale product manufacture
Source active drug substances, raw materials and packaging for laboratory scale through to commercial scale product manufacture
Conduct stability trials on product prototypes and commercial products for the purposes of determining physical and chemical stability, packaging compatibility and shelf-life
Project management of product research and development programs
Liase with manufacturers of aerosol products, solid dosage forms and liquid dosage forms for the purposes of improving manufacturing methods and product quality
Preparation of technical reports and product dossiers for Soltec technologies
Technical assistance for technology transfer
Technical assistance for internal Business Development and Marketing
Representing the company attend conferences, technical discussions, trade shows and seminars

Key Achievements
Development of commercially successful intellectual property and patented products
Development of novel and improved technologies for the delivery of consumer product formulations

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Job Details May 1987 - July 1988
Laboratory Assistant
Soltec Research Pty Ltd

Responsibilities
Perform routine laboratory tasks
Acquire hands-on experience and familiarity with common manufacturing equipment and processes in the cGMP manufacture of pharmaceuticals, cosmetics, agricultural, household and aerosol products.

Reason for Leaving Position Promotion

Short Courses

December 1997

How to Supervise People

Fred Pryor Seminars

August 2000
Problem Solving & Decision Making
Kepner Tregoe

August 2000
Consultative Relationship Development
Maura Fay

August 2000
Edward de Bono's Six Hats Thinking
Advanced Practical Thinking Training Inc.

September 2000
Edward de Bono's Lateral Thinking
Advanced Practical Thinking Training Inc.

October 2000
Project Management
Kepner Tregoe

November 2000
Microsoft Project 98 Levels 1&2
Pollak Partners

January 2001
Time Management
Australian Institute of Management

May 2002
The New Supervisor
Australian Institute of Management

May 2003
International Patent Law for Managers, Engineers and Scientists
The Center For Professional Advancement

Current Licenses & Accreditation

Drivers' Licence
Fork Lift Operator Licence

Current Professional Membership & Registrations

Association of Profession Engineers, Scientists and Managers Australia
Australian Society of Cosmetic Chemists
Monash Alumni Association Inc.

Languages

First Language English

Other Languages
Slovenian - Fluent
Croatian - Fluent
German - Conversational & Written Expression
Italian – Conversational
French - Conversational

Personal Strengths & Other Competencies

Key Strengths & Skills

Administration - Competent
Budget Preparation - Competent
Computer Literacy - Advanced
Human Resources - Basic
Intellectual Property - Competent
Marketing - Competent
Project Management - Expert
Regulatory Affairs - Competent

Other Key Strengths & Skills

Lateral thinker
Team Player
Commitment to quality, customer service and customer satisfaction
Ability to match theory with reality
Problem solving skills
Interpersonal skills
Chemical industry experience
Pharmaceutical industry experience
Aerosol product experience
OH&S Representative
Member of OH&S Committee
Member of Innovation Management Team
Involvement in cGMP Manufacturing
Involvement in cGMP Clinical Trials
Preparation of Product Development Proposals
Mechanical aptitude
Common sense

TABLE I

The following formulations were prepared:

Sample A: EXAMPLE 1 from the subject patent application

ITEM	INGREDIENT	%w/w
1	Clotrimazole	2.00
2	Caprylyl pyrrolidone	10.00
3	PEG 400	60.50
4	Cocamidopropyl Betaine	2.50
5	Sodium Cocoamphacetate	4.00
6	Sodium Lauryl Ether Sulfate	7.00
7	Ammonium Lauryl Sulfate	10.00
8	Hydroxypropylcellulose	4.00

Manufactured as per method disclosed in the subject patent application.

Sample B: Based on EXAMPLE 3 from US patent 5,866,152

ITEM	INGREDIENT	%w/w
1	Triethanolamine lauryl sulfate	66.70
2	Clotrimazole	2.00
3	Propylene glycol	5.00
4	Distilled water	26.30

Manufactured as per method disclosed in US patent 5,866,152

The final sample formulation is also based on EXAMPLE 3 from US patent 5,866,152. In this case the order of addition is changed to match as closely as possible the manufacturing procedure disclosed in subject application.

Sample C

ITEM	INGREDIENT	%w/w
1	Propylene glycol	5.00
2	Clotrimazole	2.00
3	Triethanolamine lauryl sulfate	66.70
4	Distilled water	26.30

The manufacturing procedure is as follows:

1. Combine together the propylene glycol and the clotrimazole.
2. With stirring, gently warm to ~80 °C to assist with dissolving the clotrimazole. Remove from heat.
3. Continue stirring and add the triethanolamine lauryl sulfate and distilled water. Making sure that each component is mixed in well prior to the next addition

4. If required, filter out any particulates

All the formulation examples prepared were left undisturbed on the laboratory bench to de-aerate prior to storage. Each formulation was filled into 3 x 125mL glass jars with screw top lids. One jar was stored at each of the following temperatures: 5°C, 25°C and at room temperature. Each jar was examined at the initial, 24 hour and 7 day time points and photos taken to record observations.

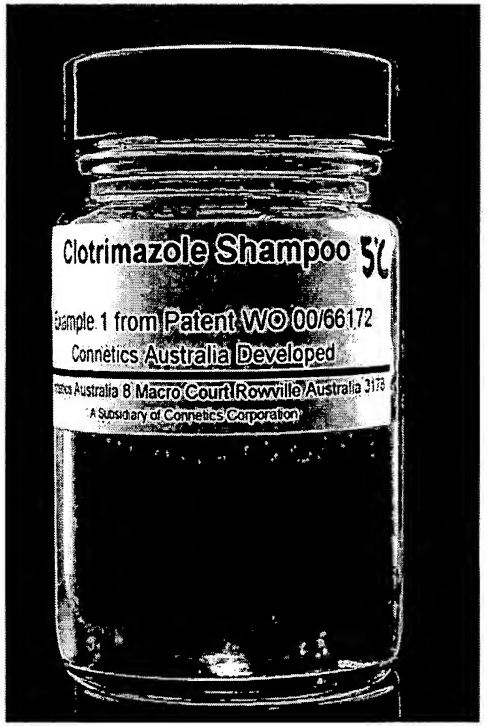
TABLE 2

Formulation Details	Time Point	Observations
EXAMPLE 1 from the subject patent application	Initial	Pale yellow liquid with a slightly hazy appearance. No visible particulates or crystals present.
	24 hours	At all temperatures the liquid samples had a pale yellow, hazy appearance. There were no visible particulates nor crystals present.
	7 days	The yellow colour of the liquid samples had a greater intensity as storage temperature increased. There was a transition from a pale yellow colour at 5°C and room temperature to a distinct yellow colour at 25°C. All samples also had a hazy appearance but there were no visible particulates nor any crystals present.
EXAMPLE 3 from US patent 5,866,152	Initial	Cloudy, pale yellow liquid. There was a layer of crystalline material that had settled to the bottom of the glass jar.
	24 hours	At all temperatures the samples had a pale yellow, cloudy appearance with a layer of crystalline material that had settled to the bottom of the glass jar
	7 days	At all temperatures the samples had a pale yellow colour but the 5°C sample had a hazy appearance to it whereas the liquid in the room temperature and 25°C samples were clear. All the samples had a 1 to 2mm layer of crystalline material that had settled to the bottom of the glass jar.
EXAMPLE 3 from US patent 5,866,152 made in accordance to EXAMPLE 1 from the subject patent application	Initial	Pale yellow liquid with a slight hazy appearance. No visible particulates or crystals present.
	24 hours	At all temperatures the samples were pale yellow, clear liquids with a fine layer of crystalline material that had settled to the bottom of the glass jar
	7 days	At all temperatures the samples had a pale yellow colour but the 5°C sample had a hazy appearance to it whereas the liquid in the room temperature and 25°C samples were clear. All of the samples had a 1 to 2mm layer of crystalline material that had settled to the bottom of the glass jar.

Figure 1: Sample A – 5°C. Example 1 from the subject Patent application.
Photos taken using the Canon PowerShot A400, asset number 00599

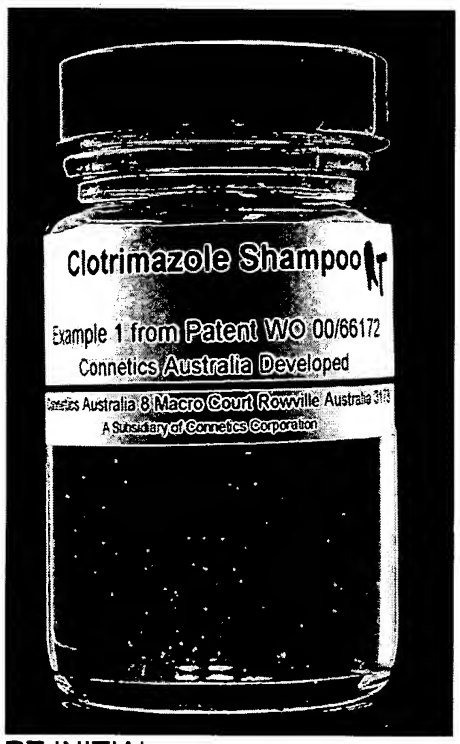
5°C INITIAL

5°C AFTER 24 Hrs

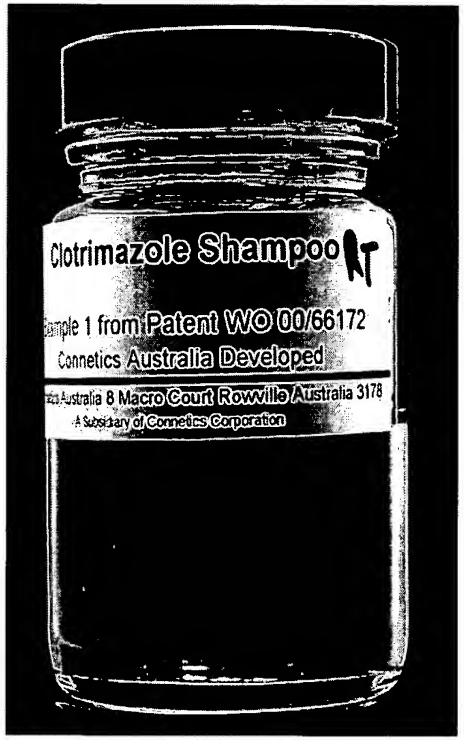


5°C AFTER 7 Days

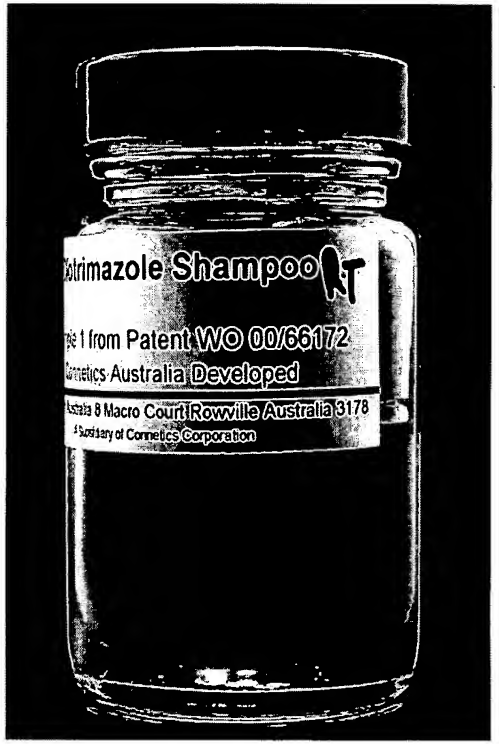
Figure 2: Sample A – Room Temperature. Example 1 from the subject Patent application.
Photos taken using the Canon PowerShot A400, asset number 00599



RT INITIAL



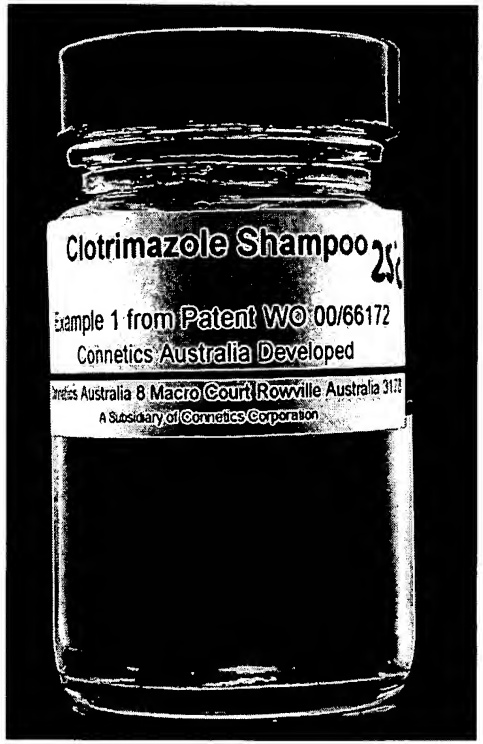
RT AFTER 24 Hrs



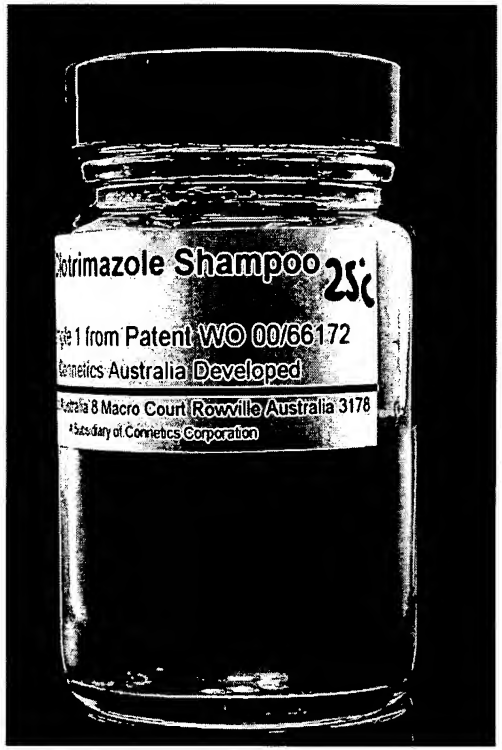
RT AFTER 7 Days

Figure 3: Sample A – 25°C. Example 1 from the subject Patent application.
Photos taken using the Canon PowerShot A400, asset number 00599

25°C INITIAL



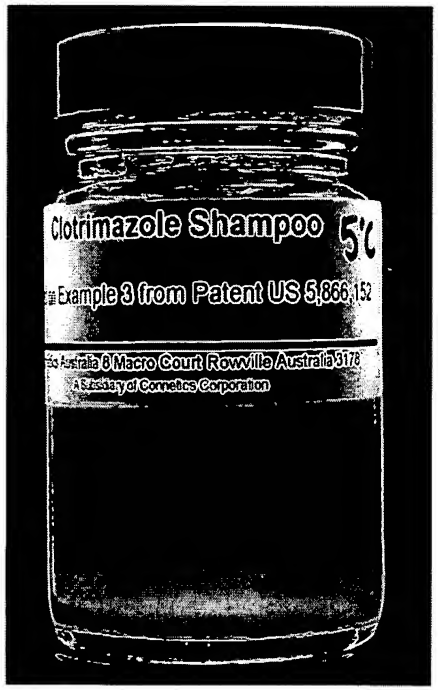
25°C AFTER 24 Hrs



25°C AFTER 7 Days

Figure 4: Sample B – 5°C. Example 3 from US Patent Number 5,866,152
Photos taken using the Canon PowerShot A400, asset number 00599

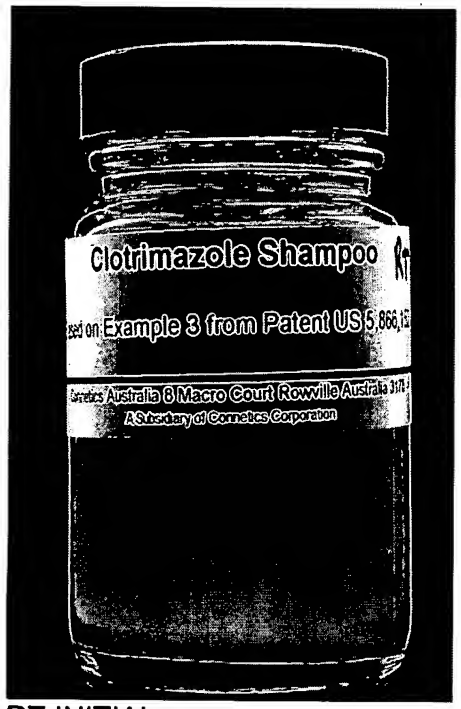
5°C INITIAL



5°C AFTER 24 Hrs

5°C AFTER 7 Days

Figure 5: Sample B – Room Temperature. Example 3 from US Patent Number 5,866,152
Photos taken using the Canon PowerShot A400, asset number 00599



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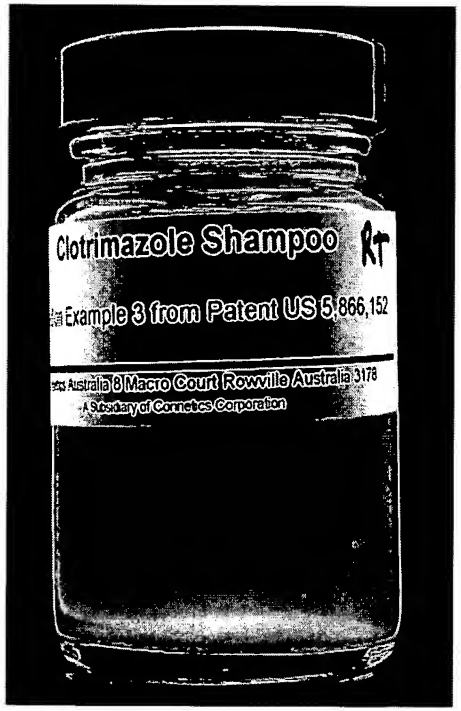
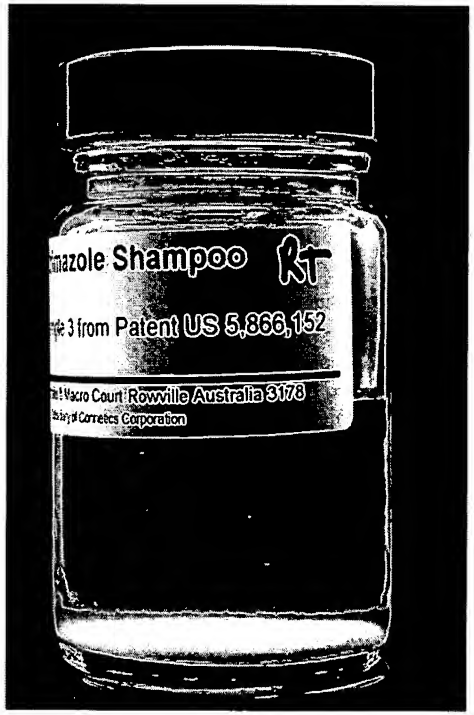
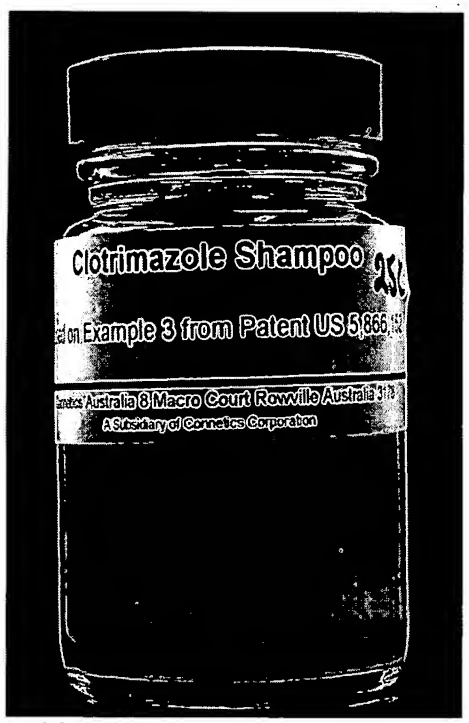


RT AFTER 24 Hrs

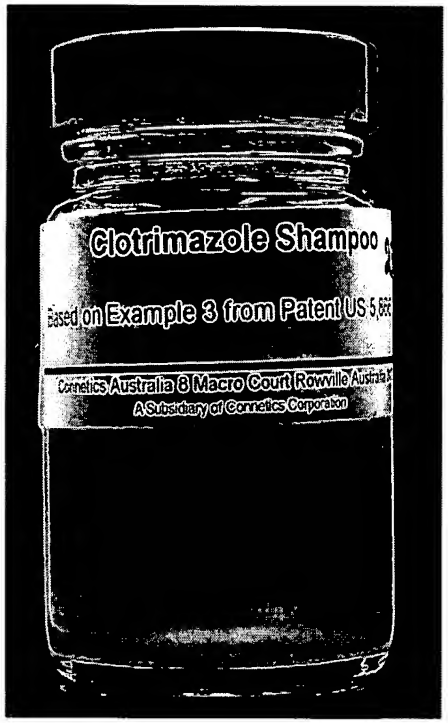


RT AFTER 7 Days

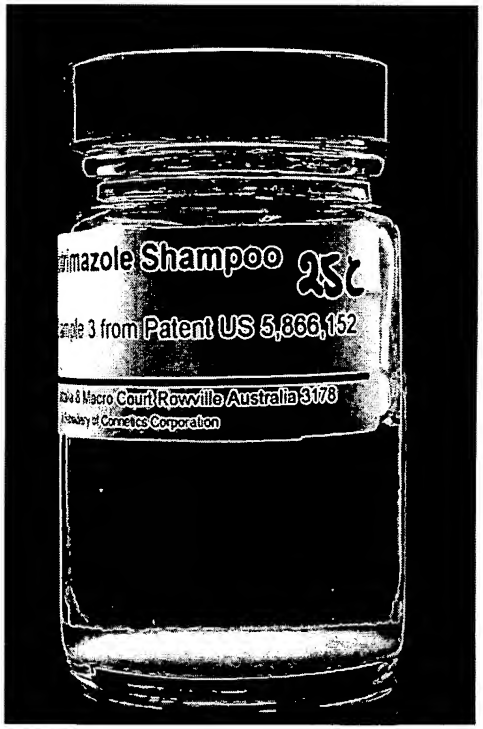
Figure 6: Sample B – 25°C. Example 3 from US Patent Number 5,866,152
Photos taken using the Canon PowerShot A400, asset number 00599



25°C INITIAL



25°C AFTER 24 Hrs

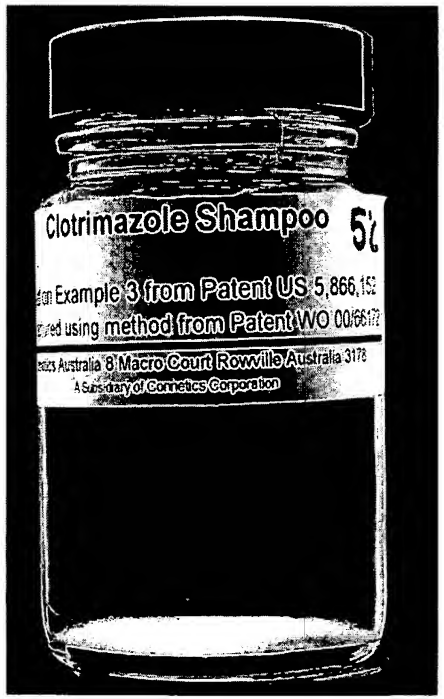


25°C AFTER 7 Days

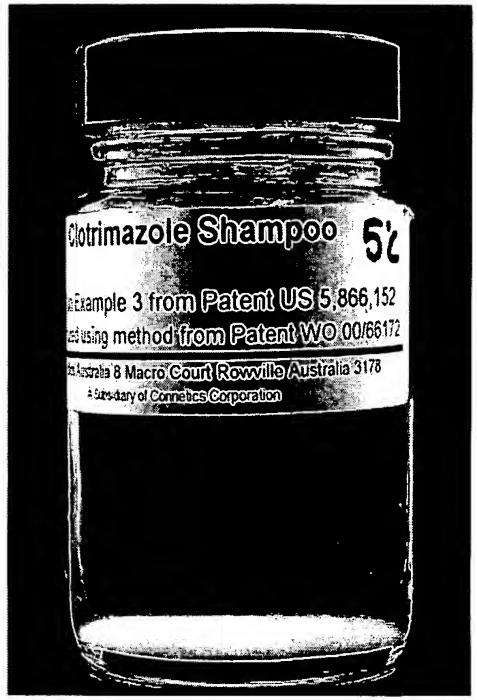
Figure 7: Sample C – 5°C. Example 3 from US Patent Number 5,866,152 manufactured as per the subject Patent application.

Photos taken using the Canon PowerShot A400, asset number 00599

5°C INITIAL



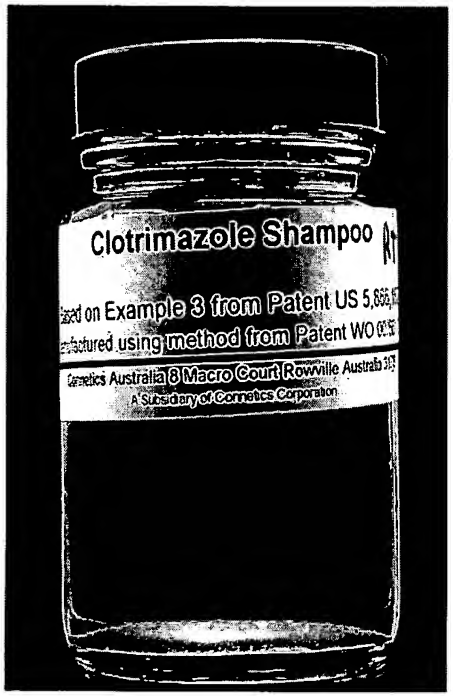
5°C AFTER 24 Hrs



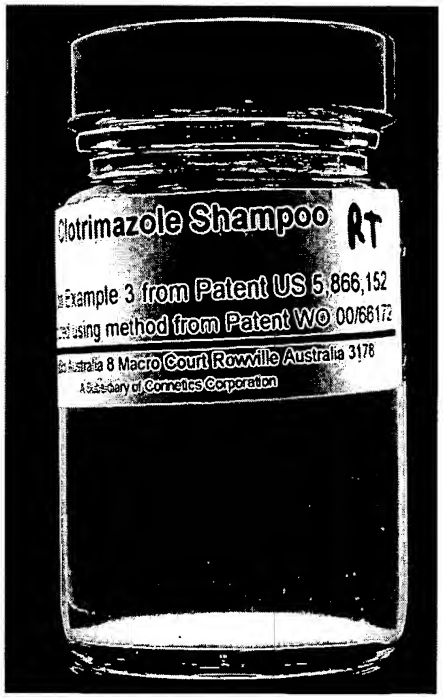
5°C AFTER 7 Days

Figure 8: Sample C – Room Temperature. Example 3 from US Patent Number 5,866,152 manufactured as per the subject Patent application.

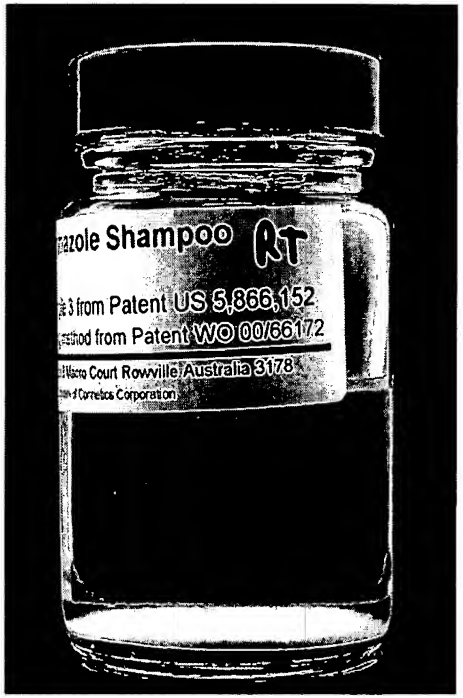
Photos taken using the Canon PowerShot A400, asset number 00599



RT INITIAL



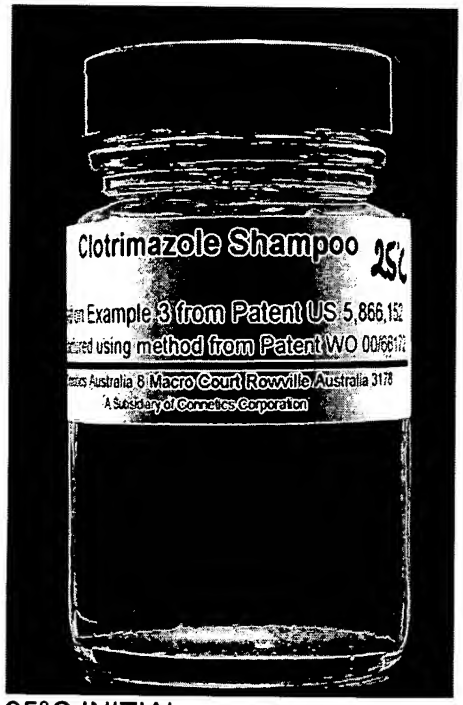
RT AFTER 24 Hrs



RT AFTER 7 Days

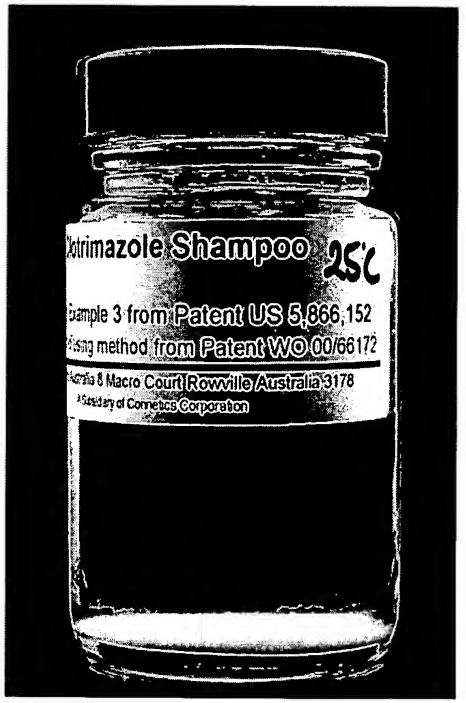
Figure 9: Sample C – 25°C. Example 3 from US Patent Number 5,866,152 manufactured as per the subject Patent application.

Photos taken using the Canon PowerShot A400, asset number 00599



25°C INITIAL

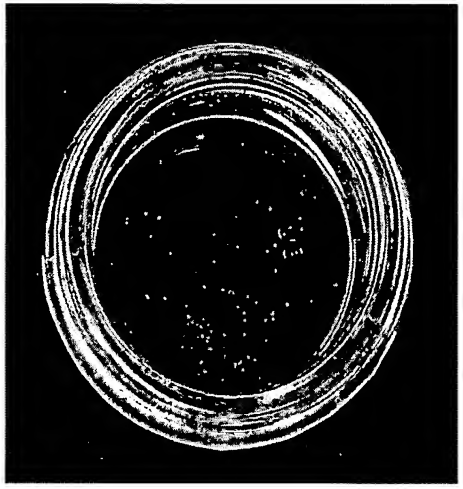
25°C AFTER 24 Hrs

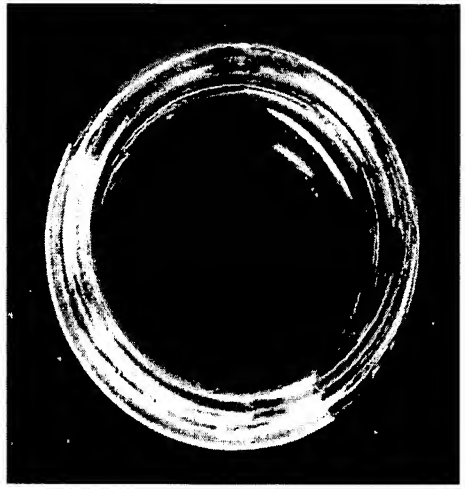


25°C AFTER 7 Days

Figure 10: Sample A. Example 1 from subject Patent application.
Photos taken using the Canon PowerShot A400, asset number 00599

CLOSE-UP PHOTOS OF FORMULATION AFTER 7 DAYS STORAGE (INSIDE THE GLASS JAR)


5°C after 7 Days


RT after 7 Days

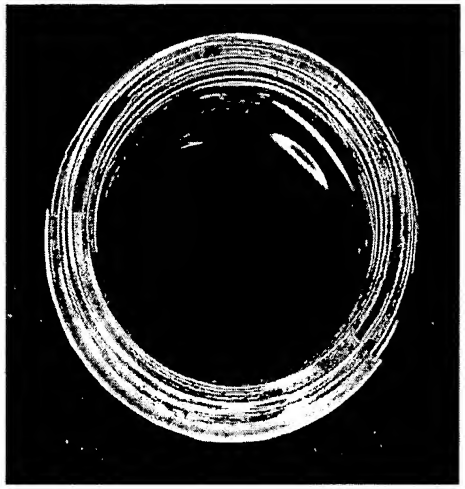
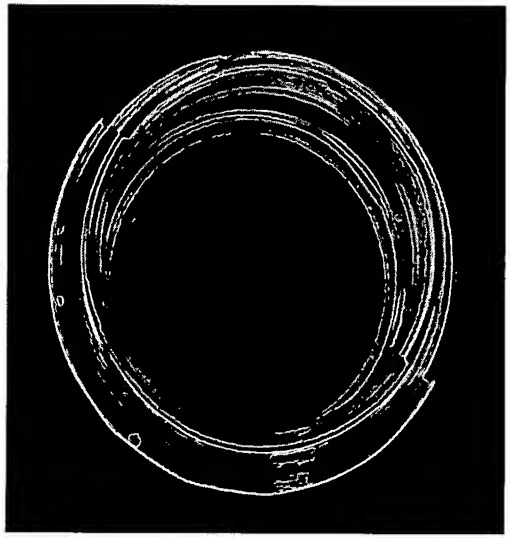
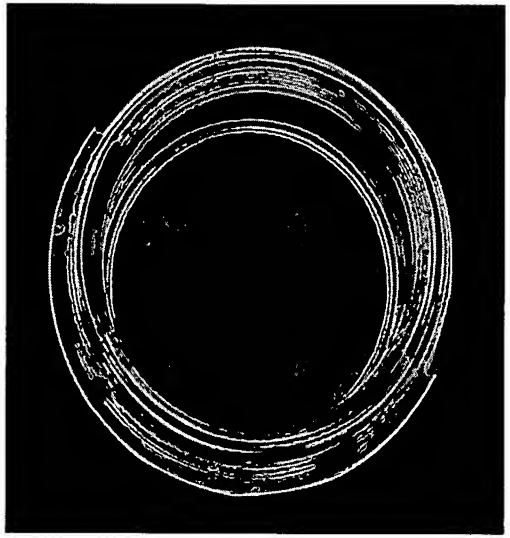

25°C after 7 Days

Figure 11: Sample B. Example 3 from US Patent Number 5,866,152
Photos taken using the Canon PowerShot A400, asset number 00599

CLOSE-UP PHOTOS OF FORMULATION AFTER 7 DAYS STORAGE (INSIDE THE GLASS JAR)


5°C after 7 Days


RT after 7 Days

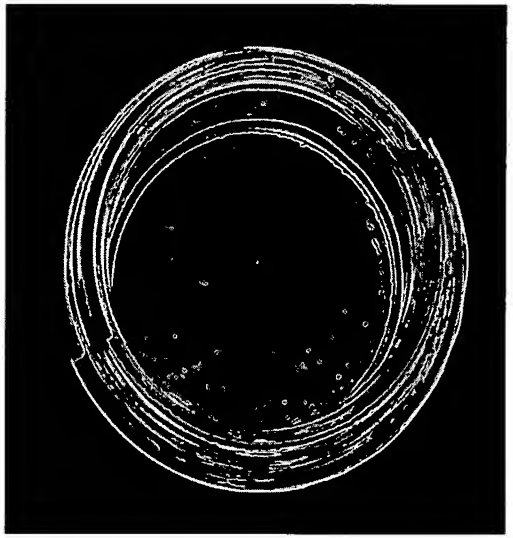
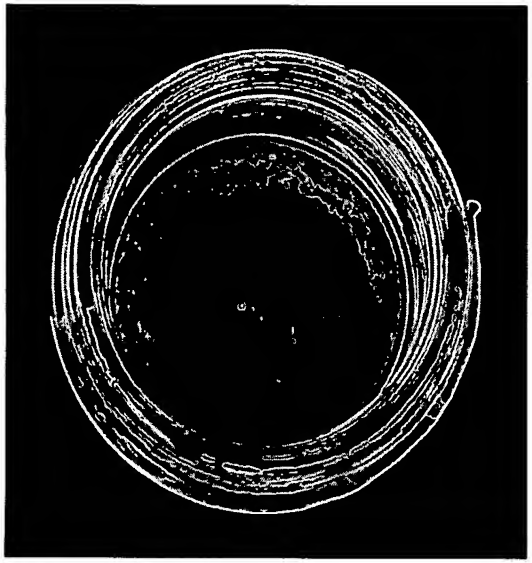
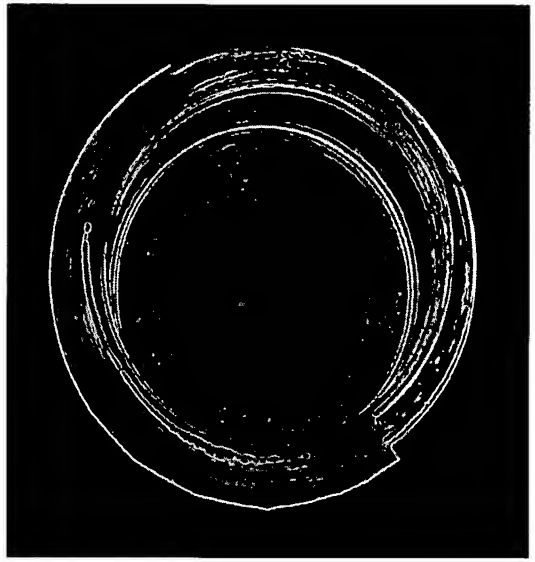

25°C after 7 Days

Figure 12: Sample C. Example 3 from US Patent Number 5,866,152 manufactured as per the patent subject application. Photos taken using the Canon PowerShot A400, asset number 00599

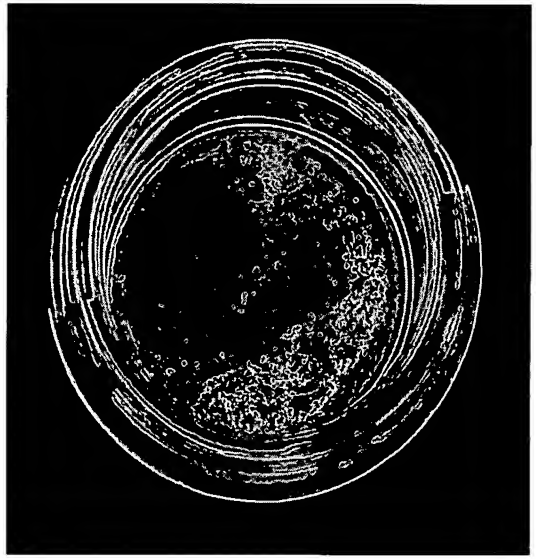
CLOSE-UP PHOTOS OF FORMULATION AFTER 7 DAYS STORAGE (INSIDE THE GLASS JAR)



5°C after 7 days



RT after 7 days



25°C after 7 days